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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	6

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,747	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,4,6-8,21,23 and 25-27* is/are allowed.

6)☒ Claim(s) *3,5,9-20,22,24,28-44 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to claims 8 and 27 is withdrawn in light of the claim amendments.

3. The rejection of claims 1-49 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.

4. The rejection of claims 1-49 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments.

5. The rejection of claims 1-49 under 35 U.S.C. 112, 1st paragraph, requiring a deposit of the seed of plant PH6ME, is withdrawn, in light of the deposit.

Claim Rejections - 35 USC § 112

6. Claims 3, 5, 12, 13, 22, 24, 30-33, 40-44, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3 and 22: the recitation "wherein said plant is manipulated to be male sterile" renders the claim indefinite. It is not clear if the claim is directed towards detasseled plants, or

plants that have been transformed with a gene conferring male sterility. The following amendments are suggested: 1) in claims 3 and 22, replace "manipulated to be male sterile" with --detasseled--; 2) add a new claim 50 directed towards a method of producing a transgenic male sterile maize plant comprising transforming the maize plant of claim 2 or 21 with a transgene that confers male sterility, and a new claim 51 directed towards a transgenic male-sterile maize plant produced by the method of claim 50.

In claims 5 and 24: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claims, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of cells of claim 4 or 23.

In claims 12, 31, and 40: the claim is indefinite because the recitation "comprising" in line 1 does not clearly indicate how many crosses are to be performed by the method. It is suggested that the recitation -- F1-- be inserted into line 1 of claims 12 and 31 after "producing a", and --F1 hybrid-- be inserted in claim 40, lines 1 and 6, before "maize".

In claims 30 and 47: the recitation "essentially unchanged" renders the claims indefinite. It is not clear what is meant by this recitation. If the maize plant of claim 21, for example, comprises further genes, then it is changed. It is not clear what is meant by the term "essentially."

In claim 33: it is not clear what is meant by a pedigree being within 2 or less crosses to a plant other than PH6ME. There is also insufficient antecedent basis for the recitation "the pedigree".

7. Claims 9-14, 17-20, 28-33, 36-39, 41-44, and 47-49 remain and claims 15, 16, 34, 35, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 06 August 2002 under item 4. Applicants traverse the rejection in the paper filed 28 October 2002. Applicants' arguments have been fully considered but were not found fully persuasive.

Applicants argue that the amendments to claims 3 and 22 obviate the rejection (response, paragraph bridging pages 11-12). The amendments do overcome the rejection, and the rejection has been withdrawn from claims 3 and 22.

Applicants argue that because of the linked genes fixed in PH6ME, one can cross PH6ME with another line, select a plant expressing at least 2 PH6ME traits and a trait from the other plant line (response, page 12, 2nd full paragraph). However, the other parent could also express the some of the same traits as PH6ME and pass it on to the progeny. Further, the traits inherited from the other parent are not known, since the description of the other parent is not provided.

Applicants argue that the reason for using traits as a means of description is because it is technically impossible to sequence the entire genome of a specific variety. Applicants continue, drawing analogy to *Ex Parte Tanksley*, in which the Examiner desired that claims recite sequence data in order to better characterize a cDNA and facilitate a prior art search. The Board treated the written description rejection as a rejection under 112 2nd paragraph and held that the Examiner may not dictate the literal terms of claims for the stated purpose of facilitating a prior

art search (response, page 13, 1st full paragraph to page 14, 1st full paragraph). However, the situation in *Ex Parte Tanksley* is not analogous. Applicants are not being required to define or describe the claimed subject matter in any particular manner. Rather, here Applicants have not sufficiently described any descendent of PH6ME in any manner. No descendent of PH6ME would express all of its morphological and physiological traits, unless it is a progeny of a self-cross.

Applicants continue, arguing that amended claims 17, 33, and 36 limit the progeny covered to those within two outcrosses from PH6ME, and the progeny of claim 41 to one outcross, and to those of ordinary skill in the art, this indicates that a line that is fewer crosses away from a starting line will be, as a whole, more highly related to the starting line, and the work of the original breeder in developing the starting line will be retained in the closely related progeny (response, page 14, 2nd full paragraph). However, the progeny will also retain the material inherited from the other plants involved in the crosses, which are not described by the specification. The progeny plants would be closely related to the other parent as well. Regarding Applicants' comment about the acceptance of traits by the Office to satisfy written description: In claim 14, Applicants are requiring the progeny of the deposited line to express only two traits that also expressed by PH6ME. Clearly, plants express many more traits than just two. The traits enumerated in the claims are also not unique to PH6ME, and therefore describing a plant by saying that it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits. Further, only claim 14 requires the plant to express 2 traits from a Markush listing. The other claims place no limitations on the traits that can be expressed, and can include undescribed traits that are not expressed by PH6ME. Further, claims 17, 33, and 36

do not limit the progeny to be within 2 outcrosses of PH6ME. The term "comprises" leaves the steps involved in the method open. Further, the method can comprise 2 or less outcrosses to any plant that has PH6ME as a progenitor. A plant that has PH6ME as a progenitor does not necessarily have PH6ME as one of its two immediate parents. Applicant also argues that it is standard practice within the plant breeding industry for licensors of inbred maize lines to retain a royalty from lines developed through the use of their inbreds, and that this provides evidence that those of ordinary skill in the art of plant breeding describe progeny in terms of pedigree (response, page 14, 2nd full paragraph). However, licensors pay royalties to use the licensed inbred, not the product progeny.

Applicants also argue that the mere fact that progeny are not created fails to preclude their patentability, and possession can be shown by describing distinguishing, identifying characteristics (response, paragraph bridging pages 14-15). However, only one of the claims indicates that only 2 of the listed traits need to be expressed, and those listed traits are expressed by other plants. The presence of the traits themselves does not distinguish the claimed plants from other plants that express them, nor do they provide any information of all the other traits of the claimed plants. Applicants argue that pedigree is a distinguishing characteristic that is in compliance with written description guidelines (response, paragraph bridging pages 14-15). However, a pedigree docs not describe the morphological and physiological traits of an organism. Further, it is not clear how a plant that is twenty generations removed from PH6ME is described by it.

Applicants argue that the genetics of PH6ME is described by the ATCC deposit of its seed, and by limiting the progeny to 2 or less outcrosses, the concern that the progeny are only

distantly related to PH6ME is addressed (response, page 15, 1st full paragraph). However, the deposit only describes PH6ME. It does not describe the morphological and physiological traits of any other plant. Further, all of the claimed plants are not limited to 2 or less outcrosses. Applicants attempt to draw analogy to *Enzo vs. Gen-Probe, U.S. State of Court of Appeals for the Federal Circuit*, for indicating that there are hundreds of subsequences of a deposited sequence which may also meet a claimed hybridization ratio, and for indicating that a deposited sequence is described by virtue of its having been deposited, and that various subsequences, mutations, and mixtures of those sequences are also described, and hold that question as an issue of fact (response, page 15, 1st full paragraph). However, the issue in *Enzo* and the instant rejection is not analogous. The hundreds of subsequences that may meet the claimed invention discussed in *Enzo*, and its various subsequences, mutations and mixtures, must still have the properties of the deposited sequence, not other properties or just a portion of the properties. If the subsequences, mutations and mixtures did not have the same properties, they would not have any relation to the deposited sequence. Applicants continue the analogy to *Enzo*, arguing that the issue of whether progeny as now claimed satisfies the issue of written description is also an issue of fact. Applicants argue that one of ordinary skill would know if PH6ME were utilized in a breeding program by looking at the breeding records, and that routine molecular techniques can be used to verify whether PH6ME is within the pedigree of a line (response, paragraph bridging pages 15-16). In the instant rejection, the progeny do not express all of the morphological and physiological traits of PH6ME, unless it is a product of a self-cross. Further, determination that PH6ME is an ancestor of a plant does not provide sufficient description of all of the morphological and physiological traits of that plant. Furthermore, the specification does not

describe any molecular determinants that one would need to identify any genetic material as having been derived from PH6ME or to verify that PH6ME is within its pedigree. No description has been provided concerning molecular markers that are unique to the PH6ME genome. Furtherstill, Applicant believes that it is technically impossible to sequence the entire genome of a specific variety.

Applicants emphasize that the influence of PH6ME cannot be removed from progeny that are 2 outcrosses removed from PH6ME, and the claimed progeny cannot be derived without the use of PH6ME as a parent. Applicants believe that this highlights the different perspective regarding claim scope between the Examiner and Applicant. Applicants contend that the Examiner's interpretation of the claims to progeny, as being of great breadth because a large number of plants could fall within its scope, ignores the essential limitation that only a plant developed through the use of PH6ME is within the scope of the claim (response, page 16, 1st full paragraph). However, the influence of the other ancestors of the claimed progeny plants also cannot be ignored. No description is provided at all as to the other ancestors, or the traits expressed by the progeny that are not expressed by PH6ME. As PH6ME is not the only ancestor of the progeny plants, the progeny necessarily express traits that are not expressed by PH6ME. Yet, no description is provided at all concerning those traits. Applicants argue that, to address the Examiner's concern that the PH6ME traits retained by the progeny may be derived from the non-PH6ME side of the pedigree, claim 14 has been amended to specify that the PH6ME traits were not derived from other plants used in the development of the claimed plant (response, paragraph bridging pages 16-17). However, again, two traits are not sufficient to describe a plant. The plants of claim 14 express more than just 2 of the traits listed in the claim. Applicants

have argued that PH6ME is unique, and that since PH6ME is described, that its descendents must also be described. However, while the combination of genes that produce PH6ME makes that line unique, Applicant does not provide any information as to why the genetic material itself is unique. The claimed plants do not have the complete combination of genes that produce PH6ME. As the claims are not limited to only self-crosses, all descendents do not inherit all of the genetic material of PH6ME. Descendants also inherit genetic material from other ancestors.

Applicants argue that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH6ME, and cite Berry et al. for discussing the probability of identifying the parents of a hybrid by SSR data when neither parent is known (response, page 17, 1st full paragraph). However, choices of possible parents were provided. Further, Applicants have not described any SSR, RFLP, or any other molecular markers that are unique to PH6ME. Applicants also note that a claim to the F1 hybrid made with a deposited line was expressly acknowledged by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., USPQ 2d 1865, 1873 (S.Ct. 2001)* (response, page 18, 2nd full paragraph). However, this decision concerned an issue under 35 U.S.C. 101, not written description.

Applicants also argue, regarding claims drawn towards the deposited lines further comprising one or more transgenes or single gene conversions, that examples of traits and single gene conversions are given in the specification. Applicants argue that even if more than one trait is affected by the transgene, that the genetics of PH6ME is only minimally affected, and argue that insertion of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes is a minor change (response, page 19, 1st full paragraph). However, Applicants are not considering the effect of the transgene on the morphological and physiological traits of PH6ME.

Even the novice in the art would recognize that even a single gene could potentially have a significant effect on a plant. That the addition a few more nucleotide sequences to the genome of PH6ME fails to significantly add to the total number of nucleotides, is not the point. The transgenes may be of any gene, including those that affect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from PH6ME, which are not described.

Applicants also argue, regarding the method claims, that the methods are fully described (page 19, last paragraph). However, the progeny plants of PH6ME that are required in the methods are not described, and those plants are a part of the claimed methods.

8. Claims 18-20 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plant PH6ME or a maize plant having all the morphological and physiological characteristics of PH6ME, further comprising one or more single gene conversions.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 21, lines 16-31). However, the specification does not teach any PH6ME plants comprising single gene conversions. It is not

clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

Claim Rejections - 35 USC § 102 & 103

9. Claims 9, 10, 13, 17, 28-30, 32, 33, 36, 41, 43, and 47-49 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Noble, Jr. (U.S. Patent No. 6,118,056), for the reasons of record stated in the Office action mailed 06 August 2002 under item 6. Applicants traverse the rejection in the paper received 28 October 2002. Applicants' arguments and the claim amendments were fully considered but were not found fully persuasive.

Applicants point out differences between PH6ME and PH1EM (response, page 19, 5th full paragraph). Applicants' argument was deemed sufficient to withdrawn the rejection from claims 1-8, 11, 12, 14-16, 18-27, 31, 34, 35, 37-40, 42, and 44. Claims 45 and 46 are cancelled.

Applicants argue that the claimed progeny plants of claims 17 and 36 are limited to plants that are two crosses away from PH6ME (response, page 20, 2nd full paragraph). Applicants argue that the plants of claim 41 are one outcross from PH6ME, and that the plants of claim 43 are produced by selfing the plants of claim 41 (response, paragraph bridging pages 20-21). However, not all of the claimed progeny plants are limited to be within two crosses of PH6ME. PH6ME has only been described in the specification by phenotypic characteristics and not by genotype. The instant claims do not place any restrictions on the properties expressed by the plants. The claimed plants then cannot be distinguished from prior art plants based on phenotype. While the combination of genes in the genome of PH6ME may be unique, the specification does not teach that any particular gene is unique. Further, no molecular markers are taught that are unique to the PH6ME genome, so one cannot determine the differences in the instantly claimed progeny plants from those of the prior art based on an analysis of the genome.

A prior art plant having the same characteristics as the instantly claimed plant would anticipate the claimed plant even if it were made by a different method (i.e. different parent or ancestor plants). As the rejected claims do not place any limitations on the properties of the claimed progeny plants and seeds, the Examiner does not have sufficient facts to determine whether the progeny plants and seeds are inherently the same. The Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the plants differ from teachings of the reference. Where the prior art product seems to be identical, except that the prior art is silent as to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 UPSQ 430, 433 (CCPA 1977).

Regarding claims 30 and 47: these claims, and those dependent thereon, are included because of the uncertainty of the recitation "essentially unchanged," as discussed above. Because of this recitation, plant PHIEM can be considered to have essentially the same morphology and physiology of PH6ME, and the reference teaches PH1EM further having a transgene or single gene conversion.

10. Claims 1, 2, 4, 6-8, 21, 23, and 25-27 are allowed. Claims 3, 5, 9-20, 22, 24, 28-44, and 47-49 remain rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can

normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 9, 2003

ASHWIN D. MEHTA, PH.D
PATENT EXAMINER